

1235WOORD01 2004-09 02

- 9 -

Claims

1. A compliance monitor for a drug delivery device for administering a drug, comprising:
 - a switch actuatable by a user on delivering a dose from the device;
 - a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and
 - a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated.
2. A compliance monitor according to claim 1, which does not affect the normal operation of the drug delivery device.
3. A compliance monitor according to claim 1 or 2, which is removably attachable to the drug delivery device.
4. A compliance monitor according to any preceding claim, comprising a clock coupled to the processor and in which the time of actuation of the switch is recorded.
5. A compliance monitor according to any preceding claim, proper positioning of the drug delivery device being positioning in contact with or relative to the user's mouth, nose or skin, as appropriate for administration of the drug.
6. A compliance monitor according to any preceding claim, the drug delivery device being for topical administration of the drug.
7. A compliance monitor according to any preceding claim, the drug delivery device being for oral administration of the drug, preferably by inhalation.
8. A compliance monitor according to any preceding claim, the drug delivery device being an inhaler operated by the user depressing a pressurised canister containing the drug, and in which the switch is a pressure-operated switch actuatable as the user depresses the canister.
9. A compliance monitor according to any preceding claim, the drug delivery device being a dry powder inhaler, a pressurised metered dose inhaler or a nebuliser.

1235WOORD01 2004-09 02

- 10 -

10. A compliance monitor according to any preceding claim, in which the sensor is a temperature sensor for sensing body temperature, for example mouth temperature.
11. A compliance monitor according to any preceding claim, in which the sensor is a light sensor for sensing when the sensor is covered, for example by the mouth.
12. A compliance monitor according to any preceding claim, in which the sensor is a conductivity sensor for sensing body conductivity, for example mouth conductivity.
13. A compliance monitor according to any preceding claim, in which a change in an output of the sensor characteristic of correct use of the drug delivery device is used to determine whether the device was properly positioned when the dose was delivered.
14. A compliance monitor according to any preceding claim, further comprising an output for downloading data to a docking station or a computer.
15. A compliance monitor according to any preceding claim, in which the data comprises a compliance record of use of the drug delivery device, including a record of whether the sensor output indicates that the device was properly positioned on each occasion that a dose has been delivered.
16. A docking station for use with a compliance monitor as defined in any of claims 1 to 15.
17. A computer-readable medium carrying a computer program for programming a general purpose computer to receive and process data downloaded from a compliance monitor as defined in any of claims 1 to 15.
18. A drug delivery device comprising a compliance monitor as defined in any of claims 1 to 15.
19. A method of using a compliance monitor to monitor use of a drug delivery device for administration of a drug, comprising the steps of;
determining when a user operates the device to deliver a dose of the drug;

sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered; and

recording for each operation of the device whether or not the device was properly positioned.

1235WOORD01 2004-09 02

- 11 -

20. A method according to claim 19, further comprising the step of determining and recording the time of each operation of the device.
21. A method according to claim 19 or 20, in which the drug delivery device is for oral administration of the drug and proper positioning of the device is proper positioning in the user's mouth.
22. A method according to claim 19, 20 or 21, further comprising the step of downloading recorded data from the compliance monitor to a docking station or a computer to allow a compliance record to be reviewed, for example by a medical practitioner.
23. A compliance monitor substantially as described herein, with reference to the drawings.
24. A compliance monitoring method substantially as described herein, with reference to the drawings.